

cell cycle, whereby the regulatory effect of the treatment is determined by comparing the initial status of the lymphocytic cell cycle and the post-treatment status of the lymphocytic cell cycle, wherein the step of preparing the lysate from the blood sample further comprises the steps of: isolating lymphocytes from the blood sample; propagating the isolated lymphocytes; and preparing a lysate from the propagated lymphocytes.

In Claim 39, line 1, change "41" to -- 38 --.

### RESPONSE TO RESTRICTION REQUIREMENT

Applicants do not traverse the Examiner's position that the application can be considered to have claims that can be categorized into at least four "distinct" inventions. Applicants do, however, respectfully request partial reconsideration of the four-way restriction requirement based on the relative burdens of additional examination placed on the Examiner and the costs that a four-way restriction would cause Applicants in pursuing four divisional applications.

The statutory basis for a restriction requirement is, of course, 35 U.S.C. § 121, which provides that: "If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. . . ." The Office Action does not assert that the inventions as claimed are "independent," but only that the claims are "distinct." The test for "distinct" inventions as claimed is that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof; process and apparatus for its practice; process and product made, etc., but are capable of separate manufacture, use, or sale as claimed and are patentable (novel and unobvious) over each other. See MPEP 802.01.

According to Office procedure, however, another test for requiring restriction is that there must be a serious burden on the examiner if restriction is not required. See MPEP 803 and 808.02.

Applicants do not traverse the restriction requirement as between Groups I and II. Applicants respectfully request reconsideration of the requirement for further restriction regarding the distinct Groups III and IV. The subject matter of Group III includes Claim 32, which is dependent from independent Claim 28. Based on the amendment of independent Claim 28, independent Claim 28 is now in Group I. The subject matter of Group IV includes Claims 8-19 and 21, which are dependent from originally-filed independent Claim 1, in Group I. (Claims 40-48 are also in Group IV.) The examination for patentability of the subject matter of Group I would necessarily require an examination including the field of search for the subject matter of Groups III and IV.

Applicants also request the Examiner to exercise his discretionary authority by balancing any additional examination burden that might be placed on the Examiner in considering Group I and the subject matter of claims dependent from the claims in Group I against the substantial additional